FILED
MAR 29 1999
OFFICE OF THE CLERK

No. 98-1284

In The

Supreme Court of the United States

October Term, 1998

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

GREGORIA GRIJALVA, MARY LEA, JOSEPHINE BALESTRERI, FRED S. SCHERZ, KEVIN A. DRISCOLL, MINA AMES, EDMUNDO B. CARDENAS, ARLINE T. DONOHO, GOLDIE M. POWELL, and RICHARD BAXTER, as individuals and representatives of a class of persons similarly situated,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

LENORE E. GERARD
Legal Assistance to the Elderly
1453 Mission St., Ste. 500
San Francisco, CA 94103
(415) 861-4444

CAROL S. JIMENEZ
5182 Katella Ave., Ste. 106
Los Alamitos, CA 90720
(562) 430-0239

AUDREY KRAUS
Center for Health Care Rights
520 S. Lafayette Park Pl., Ste. 214
Los Angeles, CA 90057
(213) 383-4519

SALLY HART
(Counsel of Record)
Center for Medicare Advocacy, Inc.
1730 E. River Rd., Ste. 107
Tucson, AZ 85718
(520) 577-1611

GILL DEFORD
Center for Medicare Advocacy, Inc.
P.O. Box 350
Willimantic, CT 06226
(860) 456-7790

Counsel for Respondents

6988

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

REVISED STATEMENT OF QUESTIONS PRESENTED

Respondents suggest that a more accurate statement of the Questions Presented, both in content and in recognition of the Secretary's goal with this Petition, is as follows:

Whether the judgments below should be vacated, and the case remanded to the district court to begin the litigation anew, because of either (1) legislation which the Secretary explicitly declined to rely on in the court of appeals, which has made no significant change to the relevant portions of the Medicare statute, and which the Secretary has misrepresented to the Court, or (2) a recent decision of this Court which, upon objective scrutiny, has no bearing on the outcome of the instant case.

Whether the courts below correctly concluded, like other courts considering government health services delivered by HMOs, that when the federally created, mandated, and operated Medicare program contracts with private HMOs to provide Medicare benefits, their coverage decisions constitute state action.

Whether the courts below correctly concluded that the Secretary violated principles of due process, which have been recognized as a requirement in the Medicare program by numerous courts, when she did not require her contracting HMOs to provide adequate notice and hearings upon the reduction or termination of Medicare benefits.

TABLE OF CONTENTS

Page

INTRODUCTION 1

STATUTORY AND REGULATORY PROVISIONS INVOLVED 2

STATEMENT OF THE CASE 5

REASONS FOR DENYING THE WRIT 13

A. The Factual And Legal Context Of *Sullivan* Renders The Decision On State Action In That Case Of No Relevance To The Instant Case .. 13

B. The Secretary's Limited Compliance With The Remedial Order Does Not Moot The Case, And The District Court Has Continuing Jurisdiction To Consider Whether Its Order Should Be Modified 21

CONCLUSION 27

TABLE OF AUTHORITIES

Page

CASES:

Agostini v. Felton, 521 U.S. 203 (1997) 26

American Manufacturers Mutual Insurance Co. v. Sullivan, 119 S.Ct. 977 (1999)..... *passim*

Blum v. Yaretsky, 457 U.S. 991 (1982) 12, 18

Bodimetric Health Services, Inc. v. Aetna Life & Casualty, 903 F.2d 480 (7th Cir. 1990).....5, 17

Bowen v. Kizer, 485 U.S. 386 (1988)..... 22

Catanzano v. Dowling, 60 F.3d 113 (2d Cir. 1995)...9, 16

City of Mesquite v. Aladdin's Castle, Inc., 455 U.S. 283 (1992)..... 24

Daniels v. Wadley, 926 F.Supp. 1305 (M.D.Tenn. 1996), vacated in part, 145 F.3d 1330 (6th Cir. 1998)..... 16

Edmonson v. Leesville Concrete Co., 500 U.S. 614 (1991)..... 14

FEA v. Algonquin SNG, Inc., 426 U.S. 548 (1976)..... 24

Fox v. Bowen, 656 F.Supp. 1236 (D.Conn. 1986) 9, 17

Gray Panthers v. Schweiker, 652 F.2d 146 (1980), appeal after remand, 716 F.2d 23 (D.C. Cir. 1983) ..6, 20

Grijalva v. Shalala, 152 F.3d 1115 (9th Cir. 1998)..... 12

Heckler v. Community Health Services of Crawford County, Inc., 467 U.S. 51 (1984) 17

Himmler v. Califano, 611 F.2d 137 (6th Cir. 1979)..... 9

J.K. v. Dillenberg, 836 F.Supp. 694 (D.Ariz. 1993)...9, 16

Jackson v. Metropolitan Edison Co., 419 U.S. 345 (1974)..... 16

TABLE OF AUTHORITIES – Continued

Page

Kraemer v. Heckler, 737 F.2d 214 (2d Cir. 1984) . . . 9, 17, 20

Lewis v. Continental Bank Corp., 494 U.S. 472 (1990) 22

Lugar v. Edmondson Oil Co., 457 U.S. 922 (1982) 14

Martinez v. Richardson, 472 F.2d 1121 (10th Cir. 1973), on later motion, 655 F.Supp. 95 (D.N.M. 1986), appeal dis'd, 874 F.2d 751 (10th Cir. 1989) . .6, 20

Mathews v. Diaz, 426 U.S. 67 (1976) 5

Mathews v. Eldridge, 424 U.S. 319 (1976) . . . . . *passim*

McCuin v. Sec. of H.H.S., 817 F.2d 161 (1st Cir. 1987) 6

National Independent Coal Operators' Assn. v. Kleppe, 423 U.S. 388 (1976) 24

Northeastern Fla. Chapter of the Associated Gen. Contractors v. City of Jacksonville, 508 U.S. 656 (1993) 24

Perry v. Chen, 985 F.Supp. 1197 (D.Ariz. 1996) 16

Princeton Univ. v. Schmid, 455 U.S. 100 (1982) 22

Schweiker v. McClure, 456 U.S. 188 (1982) 5, 20

Standard Oil v. U.S., 429 U.S. 17 (1976) 26

Transgo, Inc. v. Ajac Transmission Parts Corp., 768 F.2d 1001 (9th Cir. 1985) 26

U.S. Dep't of Treasury v. Galioto, 477 U.S. 556 (1986) 22

Vorster v. Bowen, 709 F.Supp. 934 (C.D.Cal. 1989) 9

West v. Atkins, 487 U.S. 42 (1988) 18, 19

TABLE OF AUTHORITIES – Continued

Page

CONSTITUTION, STATUTES AND REGULATIONS:

Balanced Budget Act of 1997 (BBA), Pub. L. No. 105-33, § 4001, 111 Stat. 251, 275

§ 4001:

111 Stat. 281 19

111 Stat. 294 23

111 Stat. 319 24

Social Security Act, Tit. XVIII, codified at 42 U.S.C. 1395 et seq.

42 U.S.C.:

§ 1395d(a) (S.S.A. § 1812(a)) 3

§ 1395k(a)(2) (S.S.A. § 1832) 4

Social Security Act:

§ 1851(a)(2)(A) 2

§ 1851(e)(2)(C) 19

§ 1852(g) 3

§ 1852(g)(3)(B)(iii) 23

§ 1857 ..... *passim*

§ 1862(a)(1) (42 U.S.C. § 1395y(a)) 18

42 U.S.C.:

§ 1395ff (S.S.A. § 1869) 6

§ 1395mm (S.S.A. § 1876) 2, 6

§ 1395mm(c)(1) (S.S.A. § 1876(c)(1)) ... 4, 22, 24

TABLE OF AUTHORITIES – Continued

Page

§ 1395mm(c)(2)(A) (S.S.A. § 1876(c)(2)(A)) 4

§ 1395mm(c)(5)(A) (S.S.A. § 1876(c)(5)(A)) 22

§ 1395mm(c)(5)(B) (S.S.A. § 1876(c)(5)(B)) 7

42 U.S.C. § 1983 14

Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, § 114(a), 96 Stat. 324, 341 6

42 C.F.R.:

§ 405.701 *et seq.* 6

§ 405.801 *et seq.* 6

§ 409.1-409.68 5

§ 410.1-410.175 5

§ 417.1-417.694 7

MISCELLANEOUS:

62 Fed. Reg. 23368 (April 30, 1997) 11

McIlrath, *GAO Report, Medicare HMOs*, American Medical News 3 (November 18, 1996) 6

Report of testimony by Bruce C. Vladek, HCFA Administrator, at February 10, 1995 hearing of the Health Subcommittee of the House Ways and Means Committee, reported at 842 New Developments 5-7, Medicare & Medicaid Guide (CCH) 7

Rule 60(b), F.R.Civ.P. 26

S. J. Stayn, *Securing Access to Care in HMOs: Toward a Uniform Model of Grievance and Appeal Procedures*, 94 COLUM. L. REV. 1674 (1994) 8

The Medicare Coverage Issues Manual, HCFA-Pub. 6 18

INTRODUCTION

The Secretary argues that a writ of certiorari should be issued for two reasons, neither of which is well taken.

The facts and legal context of *American Manufacturers Mutual Insurance Co. v. Sullivan,* 119 S.Ct. 977 (1999), differ so dramatically from those in the instant case that *Sullivan* has no bearing on the state action issue. Here, in contrast to the workers' compensation program at issue in *Sullivan,* Medicare's status as a public entitlement mandated by congressionally established substantive standards, to which due process protections have always attached, compels the finding of state action which the courts below correctly made.

In addition, for several reasons, it is not necessary or appropriate for the decisions below to be vacated and the case remanded in light of the Balanced Budget Act (BBA), which was passed and in effect before briefing was completed in the court of appeals. First, the Secretary explicitly declined to raise this issue at the appropriate time below, apparently viewing the BBA as not relevant to the issues here raised. Second, any apparent compliance by the BBA and its implementing regulations with the judgment below responded only in small part to the deficiencies identified by the district court. Third, as the court of appeals observed, the district court may modify its order in light of later developments if the Secretary so requests and the legal standards are met; that procedure, not the vacating of the judgments below without full briefing and in the face of inaccurate and misleading statements by the Secretary, is the appropriate procedure for resolving these issues.

Furthermore, although the Secretary suggests that this case might be appropriate for plenary review, she is in error: there is no conflict between the circuits on the issues raised in this case, and the court of appeals properly applied rules of law in the state action and due process contexts which have long been settled by this Court. Indeed, the Secretary's main effort is to manipulate the BBA and *Sullivan* as the mechanisms for negating lower court decisions with which she disagrees. In her eagerness to have the lower court opinions simply disappear, the Secretary has repeatedly mischaracterized the nature of the Medicare program and the content and relevance of the BBA. The petition for a writ of certiorari should be denied and the decisions below left intact.

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The Secretary asserts that the HMO portion of the Medicare statute in effect when the district court made its decision has been superseded by entirely new Medicare+Choice legislation. That is not correct. The HMO portion of the Medicare statute and program remains in effect, with only minor changes, renamed as one of the Medicare+Choice coordinated care options allowed by the Balanced Budget Act of 1997 (BBA), Pub. L. No. 105-33, § 4001, 111 Stat. 251, 275 (Social Security Act (S.S.A.) § 1851(a)(2)(A)). Compare BBA, §§ 4001-4002, 111 Stat. 275-330 (only partially set forth in Pet.App. 70a and 100a-101a) with the prior HMO provisions, 42 U.S.C. §§ 1395mm *et seq.* Because the Secretary failed to include significant and relevant portions of the BBA in her

Appendix, the current HMO portion of the Medicare statute, including the minor changes made by the BBA, is set forth as Respondents' Appendix (Resp.App.).

Although the BBA includes an expedited HMO reconsideration determination in its appeal procedures for Medicare HMO beneficiaries, S.S.A. § 1852(g), Pet.App. 93a-101a, this change complies with only one part of the district court's remedial order. The Secretary ignores the fact that four other important parts of that order remain unmet.

Also, contrary to the Secretary's description of Medicare HMOs as making coverage determinations according to their own professional and contractual obligations without government participation or assistance, Pet.Br. 16-17, 20, the Medicare statute specifies the health services provided to beneficiaries of the program. Under Part A, these services must include:

> (1) inpatient hospital services . . . for up to 150 days . . . ;
> (2)(A) post-hospital extended care services for up to 100 days . . . ;
> (3) . . . home health services; and
> (4) in lieu of certain other benefits, hospice care. . . .

42 U.S.C. § 1395d(a). Under Part B, services that Medicare must cover include:

> (A)(i) home health services . . . ;
> (B) medical and other health services [including physician services, outpatient

> therapies and diagnostic tests, home dialysis equipment, antigens, durable medical equipment, and ambulance services] . . . ;
>
> (C) outpatient physical therapy services . . . ;
>
> (D) [certain health clinic services];
>
> (E) comprehensive outpatient rehabilitation facility services; and
>
> (F) facility services furnished in connection with surgical procedures specified by the Secretary. . . .

42 U.S.C. § 1395k(a)(2). These provisions remain intact under the BBA.

HMOs which contract with the Medicare program are required to provide their enrollees with the full range of services covered by Medicare for beneficiaries generally. 42 U.S.C. § 1395mm(c)(2)(A). This section also remains intact under the BBA.

Congress included a mandatory enforcement mechanism for the standards prescribed for Medicare HMOs: "The Secretary may not enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection and subsection (e) of this section with respect to members enrolled under this section." 42 U.S.C. § 1395mm(c)(1). Again, this section remains intact under the BBA. Resp. App. 7.

STATEMENT OF THE CASE

1.a. The Medicare program, established by Congress in 1965, mandates that the federal government cover specific medical services for Medicare beneficiaries. The Secretary has issued extensive regulations and administrative manuals defining with precision the package of health services covered and the process by which coverage determinations are made pursuant to the statute. 42 C.F.R. §§ 409.1-409.68, 410.1-410.175. Incident to this legislative determination, the courts have definitively established that Medicare benefits are constitutionally protected property rights. *Schweiker v. McClure*, 456 U.S. 188, 198 (1982); *Mathews v. Diaz*, 426 U.S. 67 (1976).

In the traditional fee-for-service program, which has existed since Medicare's inception in 1965, health care providers are paid directly for services already rendered to Medicare beneficiaries. The Secretary contracts with private insurers, called "intermediaries" under Part A and "carriers" under Part B, to process claims and otherwise administer the benefits. These private insurers make coverage determinations including those related to medical necessity, make payments to providers and beneficiaries, establish guidelines and utilization screens for coverage, and investigate fraudulent billing practices. This Court has determined that, in exercising their contractual duties, the fiscal intermediaries act as the Secretary's agents. *McClure*, 456 U.S. at 190; see also, *e.g.*, *Bodimetric Health Services, Inc. v. Aetna Life & Casualty*, 903 F.2d 480, 487 (7th Cir. 1990).

From Medicare's beginning, Congress has required an administrative appeal process culminating in judicial review for beneficiaries who are denied benefits. 42 U.S.C. § 1395ff. The Secretary has promulgated detailed regulations governing this appeals process. 42 C.F.R. §§ 405.701 *et seq.* and 405.801 *et seq.* It has been clearly established that the requirements of procedural due process apply to the Medicare administrative appeals system. See, *e.g.*, *McCuin v. Sec. of H.H.S.*, 817 F.2d 161, 171-175 (1st Cir. 1987); *Gray Panthers v. Schweiker*, 652 F.2d 146 (1980), appeal after remand, 716 F.2d 23 (D.C.Cir. 1983); *Martinez v. Richardson*, 472 F.2d 1121 (10th Cir. 1973), on later motion, 655 F.Supp. 95, 102-103 (D.N.M. 1986) (reaffirming original judgment under updated due process analysis), appeal dismissed, 874 F.2d 751 (10th Cir. 1989).

In 1982, Congress authorized widespread Medicare contracting with risk-based HMOs. Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, § 114(a), 96 Stat. 324, 341 (codified at 42 U.S.C. § 1395mm). Under this system, Medicare pays contracting HMOs monthly a flat fee or capitation payment to provide or cover the congressionally mandated package of services. The Secretary has actively encouraged Medicare beneficiaries to enroll in HMOs, and the growth in the number of Medicare beneficiaries enrolled in HMOs accelerated greatly in the 1990's.[1]

---

[1] In 1996, 3.8 million Medicare beneficiaries were enrolled in HMOs, more than double the 1.5 million beneficiaries enrolled just three years earlier. McIlrath, *GAO Report, Medicare HMOs*, American Medical News 3 (November 18, 1996); Report

Contrary to the Secretary's suggestion, Medicare HMOs are not analogous to private HMOs. Congress has specified the package of services that Medicare HMOs must provide, *supra* at 3, and the Secretary has elaborated upon these mandates through extensive regulations and manuals. Coverage decisions by Medicare HMOs may be appealed to the Secretary and federal court; in fact, when Congress included risk-based HMO coverage, it expanded HMO beneficiary appeal rights beyond those conferred in the Medicare fee-for-service appeal process to include failure to receive services as well as denials of payment. 42 U.S.C. § 1395mm(c)(5)(B). Extensive and detailed conditions are attached to HMO participation in the Medicare program. 42 C.F.R. §§ 417.1-417.694.

b. The Joint Statement of Facts presented to the district court in this case identified a number of problems with the Medicare HMO program. The six thick volumes of exhibits, which included declarations of named plaintiffs, other beneficiaries and professionals, excerpts from discovery, and studies and investigative reports, show a pattern of denials by HMOs, particularly of certain more costly types of health services.

Beneficiaries' primary remedy for denial of service is the administrative appeal process established by statute and regulations. But the defects of this process impair the relief which it should offer to HMO enrollees who are

---

of testimony by Bruce C. Vladek, HCFA Administrator, at February 10, 1995 hearing of the Health Subcommittee of the House Ways and Means Committee, reported at 842 New Developments 5-7, Medicare & Medicaid Guide (CCH).

denied services.[2] HMO notices of denial to beneficiaries are infrequently given and, even when given, are inadequate in content. The hearing process that follows is seriously flawed, both by its extensive delays when services are urgently needed and by the inability of beneficiaries to obtain and supply supporting evidence. As a result, most beneficiaries have no effective remedy when services are denied.

2. In an effort to correct this harmful situation, HMO-enrolled Medicare beneficiaries brought the instant lawsuit, stating four claims. First, the Secretary failed to enforce the obligations of her contracting HMOs to provide congressionally mandated services. Second, the Secretary did not enforce the requirement that her HMOs provide adequate notice when they deny coverage of such health services. Third, the Secretary's failure to provide HMO beneficiaries with a timely appeal when needed health services are denied deprives them of a meaningful hearing. Fourth, in HMO appeals the Secretary should place the burden of proof on the HMO rather than on the beneficiary. After certifying a nationwide class action, the district judge issued summary judgment for beneficiaries on counts two and three of the complaint and for the Secretary on count four. The district court specifically retained jurisdiction to resolve count one.

a. Under two separate analyses, the district court found that, contrary to the Secretary's contention, HMO service denials constituted state action. First, the court

---

[2] See generally S. J. Stayn, *Securing Access to Care in HMOs: Toward a Uniform Model of Grievance and Appeal Procedures*, 94 COLUM. L. REV. 1674 (1994).

explained that Medicare HMOs fulfill two separate functions, as insurers and as direct providers of medical care. This case challenges HMOs' performance of Medicare's insurer function; it does not challenge HMOs' performance as providers of medical care. Pet.App. 33a. Courts have consistently found that private contractors fulfilling this insurance function for Medicare act as agents of the Secretary. See *Kraemer v. Heckler*, 737 F.2d 214, 215 (2d Cir. 1984); *Himmler v. Califano*, 611 F.2d 137, 140 (6th Cir. 1979); *Vorster v. Bowen*, 709 F.Supp. 934, 936 (C.D.Cal. 1989); *Fox v. Bowen*, 656 F.Supp. 1236, 1238 (D.Conn. 1986). In the present case, the district court found that "there is nothing unique about the performance of these same duties by HMOs which warrants a contrary finding here." Pet.App. 34a.

Secondly, the court analyzed HMO denials of Medicare services under the criteria set forth in *Catanzano v. Dowling*, 60 F.3d 113 (2d Cir. 1995) (decisions by private home health agencies to deny or reduce the amount of home health care for Medicaid recipients amount to state action triggering due process rights), and in *J.K. v. Dillenberg*, 836 F.Supp. 694 (D.Ariz. 1993) (decisions by private entities that contracted with the state to perform Medicaid mandated behavioral health care duties constituted state action). As in *Catanzano* and *Dillenberg*, the district court found that the criteria for state action apply here. Specifically, the district court found that, with respect to Medicare HMO service denials: (1) the government pays for covered services; (2) the government regulates HMOs' activities as they apply to Medicare beneficiaries, especially benefit coverage determinations; (3) the Secretary issues regulations and directives which cannot be

ignored, and creates the legal framework which governs the activities complained of by beneficiaries; and (4) Medicare beneficiaries appeal HMO service denials directly to the Secretary, who has the power to overturn the HMO decision. Pet.App. 32a-33a.

b. The district court held that Medicare beneficiaries who are denied coverage by contracting HMOs are entitled to due process as are Medicare beneficiaries who are denied coverage in the fee-for-service system. *Id.* at 34a-35b. The court then applied the balancing test set forth by this Court in *Mathews v. Eldridge*, 424 U.S. 319 (1976), to determine the extent of procedural protections required for HMO beneficiaries by due process. Pet.App. 42a-45a. It concluded that the Secretary's current notice and hearing procedures violated due process.

Subsequently, at the court's request, both parties fully briefed their positions regarding the content of the remedial order. Court of Appeals Supplemental Excerpts of Record 1010-1078. The court ordered the parties to enter into binding settlement discussions as to the details of a meaningful notice and appeals process, with the understanding that the Secretary's right to appeal the state action issue would be preserved. When the Secretary took the position that she would not be bound by any settlement agreement, the district court considered the parties' briefing as to the specifics of the injunction and issued its judgment on March 3, 1997. Pet.App. 59a-69a. The court did not strike down Medicare legislation or regulations, but ordered the Secretary to make reforms in five specific areas of its HMO notice and appeals process.

c. On April 30, 1997, two days before the deadline for filing a notice of appeal, the Secretary published a "Final Rule with comment period", which implemented a portion of the court's order. 62 Fed. Reg. 23368 (April 30, 1997). She then requested a stay of the judgment pending appeal, claiming that her new regulations complied with many of the court's procedural requirements, and, significantly, that the other requirements would be addressed by additional regulations in the near future. Def. Motion for Stay Pending Appeal (5/13/97), in Court of Appeals Excerpts of Record (C.A.E.R.) 200. The district court granted the stay based on the Secretary's assurances regarding further compliance: "[T]he entire case may become largely moot if the Secretary's attestations regarding rule changes are true and are implemented without delay." Pet.App. 68a. However, consistent with her regrettably misleading practices throughout this litigation, the Secretary has never issued regulations implementing the rest of the district court's judgment.

d. On August 5, 1997, the Balanced Budget Act of 1997 was enacted, folding Medicare HMOs into a broader Medicare+Choice set of options. The BBA also inserted into the statute some time frames for expedited appeals.

Although the BBA was enacted before the Secretary filed her reply brief in the court of appeals, she declined to discuss the new statute. Instead, she stated without qualification that the BBA provisions "have no effect on the arguments presented in this appeal." Gov't Reply Br. at 10 n.9. Furthermore, at oral argument before the court of appeals on January 13, 1998, the Secretary again disclaimed any effect on this case by the BBA, which had become effective on January 1, 1998.

The BBA provided for expedited appeal in some but not all of the situations addressed by the district court. Unfortunately, neither it nor the Secretary's implementing regulations complied with other important protections included in the judgment below. First, they do not satisfy the five-day timeliness standard for written denial notices.[3] Second, they do not provide for an independent, non-HMO decision-maker in expedited reviews. Third, they fail to provide for urgently needed services to continue pending expedited review. Fourth, they do not implement the congressional mandate for the Secretary's enforcement of HMO contractual conditions.

3. The Ninth Circuit, in a unanimous opinion written by Judge Wiggins, affirmed the district court's decision. Pet.App. 1a-21a. First, the court of appeals held that HMO denials of services to Medicare beneficiaries constitute state action. The court considered each of the factors that point to state action, and stated that, although each factor alone might not be sufficient to establish state action, together they show that the HMOs and the federal government are joint participants in providing Medicare services. Pet.App. 9a-10a. The court distinguished *Blum v. Yaretsky*, 457 U.S. 991 (1982), where physicians made medical treatment decisions based on professional standards, from *Grijalva*, where HMOs make Medicare coverage determinations pursuant to federal law. Pet.App. 11a.

---

[3] The Petition incorrectly asserts that the five-day standard is unreasonably rigid. In fact, the judgment carefully provides for extensions of up to sixty days when needed to "make a responsibly considered medical determination." Pet.App. 60a.

The court of appeals then performed its own balancing test under *Mathews v. Eldridge*, and concluded that due process does require the procedural protections for Medicare beneficiaries enrolled in HMOs that were ordered by the district court. Pet.App. 13a.

Finally, the court addressed the Secretary's argument that intervening regulations warranted modifying the district court's injunction. Judge Wiggins noted that the district court has continuing jurisdiction over its injunction and that the Secretary could seek modification through the district court. Pet.App. 20a. As the Secretary had expressly advised the Ninth Circuit that the BBA did not change the issues before it, the court did not address the BBA.

Subsequently, the Secretary filed a Petition for Rehearing With Suggestion For Rehearing En Banc. Her petition was based largely on a reversal in position, namely, that the BBA does affect the issues and relief in this case. The panel unanimously denied the petition, and the court as a whole declined to rehear the case *en banc*. Pet.App. 22a-23a.

REASONS FOR DENYING THE WRIT

A. The Factual And Legal Context Of *Sullivan* Renders The Decision On State Action In That Case Of No Relevance To The Instant Case.

1. The Secretary's reliance on *American Manufacturers Mutual Insurance Co. v. Sullivan*, 119 S.Ct. 977 (1999), as providing grounds to vacate and remand the

decision below is misplaced. In *Sullivan*, this Court held that a private insurer's decision to withhold payment and seek utilization review of whether particular medical treatments were reasonable and necessary is not fairly attributable to the state so as to subject the insurer to the Fourteenth Amendment's constraints. Thus, although the *Sullivan* decision generally discusses this Court's state action jurisprudence, it has no specific relevance to this case and offers no basis for requiring the appeals and district courts to revisit their analyses.

a. Initially, it needs to be emphasized that *Sullivan* does not modify this Court's prior holdings on state action. While enlightening in the application of state action principles to a case under 42 U.S.C. § 1983 involving workers' compensation, *Sullivan* does not alter the analytical framework relied on by the courts below in this case. This Court reaffirmed the traditional two-step approach enunciated in *Lugar v. Edmondson Oil Co.*, 457 U.S. 922, 937 (1982), and reached its conclusion that there was no state action by distinguishing the situation in *Sullivan* from prior state action cases and by carefully parsing the factual contexts in which the different controversies arose. 119 S.Ct. at 985-989. The court of appeals' critique in the instant case is entirely consistent with this Court's long-standing approach, and *Sullivan* makes no change in those parameters previously outlined.[4]

---

[4] *Sullivan* also demonstrates that there is no significance to the Secretary's observation that the appellate courts' decisions in *Sullivan* and the instant case failed to include the three principles applicable to the second *Lugar* factor, as set out in *Edmonson v. Leesville Concrete Co.*, 500 U.S. 614, 621-622 (1991). See Pet.Br. 16. The absence of an explicit statement of these

b. It is of paramount importance to the resolution of this Petition, however, that the legal and factual context of *Sullivan* differs dramatically from the instant case. Unlike *Sullivan*, where the state action inquiry focused on private decisions to withhold payment for medical care based on professional standards, with no state obligation to pay or provide benefits, 119 S.Ct. at 986-988, the state action inquiry in the present case turns on HMO coverage determinations which are based on federal law and the governmental obligation to provide benefits.

The Secretary contends that the state action holding below was "predicate[d] . . . largely on the government's regulatory role." Pet.Br. 16. Given this Court's repeated recognition, including in *Sullivan*, 119 S.Ct. at 986, that regulation alone does not convert private action into state action, it is not surprising that the Secretary would seek to frame this case as merely an instance of government regulation. This situation, however, is vastly different from one involving a regulated industry, as the state action finding is here predicated on a comprehensive federal statutory scheme establishing the Medicare program. See *supra* at 2-4.

The structure and operation of the Medicare program, which is detailed at length in the statute, the regulations, and the manuals, are the responsibility of the Secretary to carry out and enforce, and the HMOs which contract with the Secretary play subordinate roles in this

---

principles does not necessarily undercut the implicit propriety of the lower courts' analytical approach, regardless of the ultimate outcome of those analyses.

scheme. The Secretary not only sets the benefit entitlement package, coverage and standards for quality, organization, delivery of services, and notice and appeal rights, but exercises a virtual monopsony in its role as the exclusive buyer of beneficiary services. Unlike *Sullivan*, 119 S.Ct. at 988, and *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 352-353 (1974), where the state had no obligation to provide service or benefits, in this case the government is obligated to ensure that HMOs provide all federally mandated public benefits. That is the critical difference from the instant case, where the obligation has always attached to the government.

Courts have invariably found state action in the context of government health benefits obligated by statute and provided via a delegation to HMO. In a number of recent decisions courts have explicitly rejected arguments against state action like that made by the Secretary. In *Catanzano*, 60 F.3d at 117-120, state action and consequent due process protections were found in a managed care arrangement for Medicaid benefits. In *Perry v. Chen*, 985 F.Supp. 1197 (D.Ariz. 1996), the court held that managed care organizations contracting with the state's Medicaid program must meet due process requirements when they deny health services to beneficiaries. In *Daniels v. Wadley*, 926 F.Supp. 1305, 1311 (M.D.Tenn. 1996), vacated on this point *sub nom. Daniels v. Menke*, 145 F.3d 1330 (6th Cir. 1998) (table) (vacated for change of circumstances), the district court held that Medicaid-contracting HMOs are state actors and so are subject to due process standards when they deny health services to beneficiaries. Finally, in *J.K. v. Dillenberg*, 836 F.Supp. at 697-699, state action

with constitutional protections was found in private mental health case management services provided under contract with the state Medicaid program.

c. There is no logic in according preferential treatment to HMOs which participate in the Medicare system, when, like fee-for-service providers, they contract with the federal government to carry out federally established coverage decisions and as such are acting as agents. See, *e.g., Heckler v. Community Health Services of Crawford County, Inc.*, 467 U.S. 51, 54, 64 (1984); *Bodimetric Health Services, Inc.*, 903 F.2d at 487; *Kraemer*, 737 F.2d at 215; *Fox*, 656 F.Supp. at 1238. That HMOs participate both in the Medicare program and in the private sector is not a relevant concern. Rather, it is their voluntary participation in the Medicare program and in the provision of Medicare benefits which defines their role as state actors, for, in that context, the HMOs' actions are "fairly attributable to the State." *Sullivan*, 119 S.Ct. at 989.

A finding of no state action in the HMO Medicare context, and the consequent reduction in beneficiary rights, would also create a double and unequal standard for Medicare beneficiaries, depending on whether they were HMO-enrolled or in fee-for-service. The courts below explicitly recognized this unfairness and the fact that there is nothing in the legislative record to indicate a congressional intention to create such a disparate system. See Pet.App. 34a-35a.

Further, the Secretary significantly errs by stating that the court below "conclud[ed] that *medical treatment* decisions by private HMOs concerning their Medicare-

beneficiary members are properly attributed to the federal government." Pet.Br. 16 (emphasis supplied). In fact, the court of appeals' ruling clearly was limited to *coverage decisions* by Medicare HMOs rather than medical judgments. Pet.App. 11a. By contrast, *Sullivan* did not involve coverage determinations but, rather, withholding payment to providers pending resolution of medical treatment disputes, where standards were not established by the state. 119 S.Ct. at 986.[5]

The present case is also quite different from prior cases where the challenged activity turned on judgments made by medical professionals. In *Blum v. Yaretsky*, 457 U.S. at 1008-1009, this Court held that physician treatment decisions do not involve state action. The lower courts here rightly distinguished HMO coverage determinations from the situations in *Blum* and its progeny where no state action was found. Pet.App. 8a-10a, 30a. The Secretary's attempt to insulate herself and her HMOs from accountability by cloaking them in independent professional discretion must fail. See Pet.Br. 17-18 n. 6.

The situation in this case – unlike *Sullivan* – is similar to *West v. Atkins*, 487 U.S. 42 (1988). There, the Court

---

[5] The Medicare statute contains a section listing exclusions from its package of covered services; several of the exclusions are services "not reasonable and necessary for . . . [various listed purposes]." S.S.A. § 1862(a)(1). The Secretary has further defined in detail the situations where these exclusions are found. See, *inter alia*, The Medicare Coverage Issues Manual, HCFA-Pub. 6. These Medicare coverage exclusions are not analogous to the Pennsylvania legislation analyzed in *Sullivan*, where medical judgment was a prerequisite to entitlement.

found that a state-contracted physician's delivery of medical treatment to state prison hospital inmates was action fairly attributable to the state, as it had an obligation to provide adequate medical care, it delegated that function, and the private actor voluntarily assumed the obligation by contract. *Id.* at 56. These are the same factors identified by the district and appellate courts below in concluding that there is state action in this situation. See Pet.App. 10a, 32a.

Indeed, the effect of the BBA is to accentuate the Medicare parallel to the circumstances which defined state action in *West*. Under the BBA, when beneficiaries elect to enroll in managed care organizations, they will be "locked in" and dependent on their HMOs to make coverage decisions according to federal law. S.S.A. § 1851(e)(2)(C), added by BBA § 4001, 111 Stat. 281 (misleadingly omitted from Pet.App.; see *id.* at 78a). Consequently, beneficiaries' circumstances will be remarkably similar to those of the inmates in *West*, who also had no alternative to the health care available from the contracting physician – a state actor.

e. The Secretary wrongly discerns significance in her observation that the relationship between Medicare beneficiaries and HMOs is the "product of a private choice." Pet.Br. 17. But it is irrelevant that an HMO's connection to its Medicare beneficiary members resembles the HMO relationship to private health beneficiaries on the issue of choice of plans. As this Court noted in *West*, 487 U.S. at 56 n. 15, whether the role of a putative state actor "parallels one in the private sector is not, by itself, reason to conclude that the former is not acting under color of state law in performing his duties."

The relevant private decision-making at issue in this case is not that of Medicare beneficiaries choosing the HMO route. It is, rather, the voluntary decision of private health plans to participate as contractors in the Medicare program. Consequently, like intermediaries in the traditional fee-for-service Medicare market, they must adhere to the statutory and contractual entitlements to benefits.

2. The lower courts correctly held that principles of due process require the procedural protections ordered in this case for Medicare HMOs. In *Sullivan*, this Court held that the Due Process Clause does not apply to medical benefits under the Pennsylvania workers' compensation law because there is no protected property interest in those benefits. 119 S.Ct. at 990. Here, in direct contrast, this Court, as well as numerous other courts, has long recognized that due process principles apply to the Medicare package of health benefits. *McClure*, 456 U.S. at 198; see also, *e.g.*, *Kraemer*, 737 F.2d at 222; *Gray Panthers*, 652 F.2d at 146; *Martinez*, 472 F.2d at 1121; *Martinez*, 655 F.Supp. 95, 99.

The Secretary complains that, in its due process analysis, the court of appeals did not give substantial weight to agency views, but she misquotes the court's opinion. Pet.Br. 18. Judge Wiggins rejected the Secretary's assertion that *Eldridge* confers "great deference" upon the Secretary's views on the appropriate level of procedural protection, for the simple reason that the language and standard suggested by the Secretary simply do not appear in *Eldridge*. See Pet.App. 13a n.3. In fact, the district judge did give deference to her views on this point, as he conscientiously reviewed both the Secretary's existing procedures and arguments, ruling in her favor on

one of the four counts. Pet.App. 24a *et seq.* In formulating relief, the district court asked the Secretary to file a response to the proposed judgment and then ordered beneficiaries to engage in settlement talks with the Secretary on the remaining issues. District Court Minute Entry of 2/3/97, in C.A.E.R. 199. The court of appeals reviewed the government's interests in a separate section of its opinion, and, even after applying the deference due under *Eldridge*, the court determined that the government had simply failed to advance any convincing argument that the burden on it outweighed the need for additional due process protections.

B. The Secretary's Limited Compliance With The Remedial Order Does Not Moot The Case, And The District Court Has Continuing Jurisdiction To Consider Whether Its Order Should Be Modified.

1. The Secretary's assertion that this case would warrant plenary review absent its alleged similarity with *Sullivan* is unfounded. The decisions below were not nearly so sweeping as to have "declare[d] unconstitutional the Secretary's implementation of a major federal program." Pet.Br. 20. Rather, they simply held that one circumscribed aspect of the Medicare program – appeal rights for HMO beneficiaries – needed improvement to meet judicially recognized standards. Nor did the decisions "constitutionalize" private HMOs. *Id.* HMOs conduct their activities as before, except that appeal procedures for Medicare beneficiaries, which have always been prescribed by the Secretary, are somewhat stricter.

2. Contrary to the Secretary's repeated assertions, the BBA and regulations do not substantially alter the controversy or moot this case. First, the district court's decision did not strike down any particular provisions of the Medicare statute or regulations. Rather, the court focused on the Medicare appeals process as it existed in practice, and ordered the Secretary to improve the process in certain specific ways. Pet.App. 24a-64a. Thus, the BBA did not replace legislation declared invalid by the court, and for that reason many of the decisions cited by the Secretary are not directly applicable to this case. See, *e.g., Lewis v. Continental Bank Corp.*, 494 U.S. 472 (1990); *Bowen v. Kizer*, 485 U.S. 386 (1988); *U.S. Dep't of Treasury v. Galioto*, 477 U.S. 556 (1986); *Princeton Univ. v. Schmid*, 455 U.S. 100 (1982).

Second, the BBA and the new regulations do not satisfy the requirements of the district court's remedial order. The BBA renamed Medicare risk-contracting HMOs "coordinated care plans," grouped them together with some new structures for providing Medicare benefits, and shifted some of the relevant statutory provisions to a new section of the Medicare statute. But neither the statutory framework nor the statutory provisions addressed by the lower courts have changed. Section 1395mm(c)(1) of title 42, which forbids the Secretary from entering into a contract with an HMO unless it meets the statutory requirements and upon which the lower courts relied (Pet.App. 20a, 54a), has *not* been repealed. Section 1395mm(c)(5)(A)'s requirement of meaningful procedures for hearing and resolving grievances between enrollees and the HMO also remains in the statute. See Resp.App. 7.

Although the Secretary describes in glowing detail the salubrious contents of the BBA (Pet.Br. 20-22), she fails to note that many of its procedural provisions deal with matters not raised in this litigation, such as decision-making by qualified medical personnel and the time limitation for non-expedited reconsiderations. Other BBA provisions touted in the Petition simply repeat in statutory form procedural characteristics of the existing system, such as independent review of adverse HMO reconsiderations and subsequent levels of review by ALJs and federal courts. Only one important element of the district court's remedial order is satisfied by the BBA: the requirement that an expedited HMO reconsideration by the HMO be provided within three days (or 72 hours in the BBA) for urgently needed health services. S.S.A. § 1852(g)(3)(B)(iii), added by BBA § 4001, 111 Stat. 294.

However, the other key components of the court order are not met in the BBA and the Secretary's regulations. For example, recognizing the frequent need for prompt medical treatment, the district court required that HMOs make initial determinations within five days of a request for a health care service unless more time is required by the HMO. Pet.App. 60a. The court also required the continuation of on-going and urgently needed acute care services (unless harmful to the enrollee) pending an expedited reconsideration determination. *Id.* at 63a. Finding that existing "notice and informal hearing requirements set forth by statute and regulations are all but ignored," *id.* at 51a, the court required the Secretary to enforce Congress' statutory prohibition against renewing contracts with HMOs that do not comply with federal standards. *Id.* at 54a-55a, 61a,

63a. The BBA does not satisfy these obligations, and the Secretary continues to ignore the bulk of the remedial order.

The Petition asserts that the prohibition against contracting with non-compliant HMOs was mooted by the BBA in its enactment of S.S.A. § 1857, BBA § 4001, 111 Stat. 319. Pet.Br. 24 n.13. While it is true that the new S.S.A. § 1857 uses permissive language in authorizing the Secretary to terminate non-compliant Medicare+Choice organizations generally, the Petition fails to disclose the fact that the BBA did not repeal 42 U.S.C. § 1395mm(c)(1), which mandates non-renewal of Medicare contracts with deficient HMOs. Resp.App. 7. Under the rules of statutory construction, the more specific provision of section 1395mm(c)(1) continues to be controlling in Medicare contracts with HMOs under Medicare+Choice. And where, as here, the intervening legislation and regulations do not resolve many of the underlying controversies or issues, the case is not moot. *Northeastern Fla. Chapter of the Associated Gen. Contractors v. City of Jacksonville*, 508 U.S. 656, 662 (1993) (municipal ordinance conferring minority business preferences voluntarily replaced during appeal did not moot case when replaced by similar statute); *City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 (1992) (voluntary compliance did not moot judgment). See also, *e.g.*, *National Independent Coal Operators' Assn. v. Kleppe*, 423 U.S. 388, 393 n.4 (1976) (challenge to validity of regulations regarding administrative hearings not moot where regulation reissued after filing of suit required a hearing if requested); *FEA v. Algonquin SNG, Inc.*, 426 U.S. 548, 558 n.8 (1976) (challenge to administrative imposition of fees on oil imports not mooted by new

federal statute because it did not eliminate one type of fee which respondents sought to enjoin).

3. The Secretary asks the Court to vacate the court of appeals' decision and remand this case to the district court with instructions to vacate its judgment as well and conduct such further proceedings as may be appropriate in light of the BBA and new regulations. Pet.Br. 26. This action is neither necessary nor appropriate for several reasons.

First, it is apparent that the Secretary's regulatory and legislative initiatives were in reaction to the injunction in this case. Even the Secretary should not be allowed to manipulate the judicial process by offering half a loaf after her efforts to evade compliance have failed.

As discussed above, the Secretary advised the court of appeals that it need not consider the effect of the BBA in deciding the appeal. Although that legislation became law in August 1997, before the appeal was fully briefed and argued, the Secretary informed the court that it should not consider its provisions: "[T]hese changes have *no effect* on the arguments presented in this appeal." Gov't Reply Brief at 10 n.9 (emphasis added). Furthermore, although oral argument took place after the January 1, 1998 effective date of the BBA, the Secretary still did not ask the court to consider its effect. Having expressly waived her opportunity to raise this legislation below, the Secretary should not be allowed to use it now to further delay or deny relief to tens of thousands of Medicare beneficiaries.

Second, the relief requested by the Secretary, reconsideration by the district court, may be obtained without the issuance of a writ of certiorari vacating the court of appeals' decision. The district court retained jurisdiction to consider the effects of the procedural changes ordered, Pet.App. 58a, 64a, and, in any event, the Secretary may seek modification in light of the BBA changes on remand to the district court pursuant to Rule 60(b), F.R.Civ.P. At the conclusion of his opinion for the unanimous panel below, Judge Wiggins noted precisely this point:

> The district court has continuing jurisdiction over the modification of the injunction. See *Transgo, Inc. v. Ajac Transmission Parts Corp.*, 768 F.2d 1001, 1030 (9th Cir. 1985) (declining to remand to district court with directions to modify injunction, noting that the party "may apply directly" to the district court for modification in light of post-trial events). The Secretary may move in the district court for a modification of its injunction.

Pet.App. 21a. See also, *e.g.*, *Agostini v. Felton*, 521 U.S. 203 (1997) (discussing standards for a Rule 60(b) motion); *Standard Oil v. U.S.*, 429 U.S. 17 (1976) (unsuccessful appellant may make a Rule 60(b) motion on remand).

Because the intervening legislation and regulations complied only in small part with the lower court's order, this case is far from moot. The court of appeals' opinion directing the Secretary to seek consideration of these subsequent events in the district court was correct. It is not necessary, and certainly not equitable, for this Court to vacate the decisions below merely to allow the Secretary to belatedly raise additional issues. The Secretary,

like all other litigants, should apply to the district court for that relief, rather than ask for this Court's intervention merely because of the fortuitous timing of the petition for a writ of certiorari.

CONCLUSION

For the reasons stated, the Court should deny the petition for a writ of certiorari.

Respectfully submitted,

LENORE E. GERARD
Legal Assistance
to the Elderly
1453 Mission, Ste. 500
San Francisco, CA 94103
(415) 861-4444

CAROL S. JIMENEZ
5182 Katella Ave., Ste. 106
Los Alamitos, CA 90720
(562) 430-0239

AUDREY KRAUS
Center for Health
Care Rights
520 S. Lafayette Park Pl.,
Ste. 214
Los Angeles, CA 90057
(213) 383-4519

SALLY HART
(*Counsel of Record*)
Center for Medicare
Advocacy, Inc.
1730 E. River Rd., Ste. 107
Tucson, AZ 85718
(520) 577-1611

GILL DEFORD
Center for Medicare
Advocacy, Inc.
P.O. Box 350
Willimantic, CT 06226
(860) 456-7790

Counsel for Respondents

March 29, 1999

Soc. Sec. Act § 1876 [codified 42 U.S.C. § 1395mm] PAYMENTS TO HEALTH MAINTENANCE ORGANIZATIONS AND COMPETITIVE MEDICAL PLANS

Sec. 1876. (a)(1)(A) The Secretary shall annually determine, and shall announce (in a manner intended to provide notice to interested parties) not later than September 7 before the calendar year concerned –

(i) a per capita rate of payment for each class of individuals who are enrolled under this section with an eligible organization which has entered into a risk-sharing contract and who are entitled to benefits under part A and enrolled under part B, and

(ii) a per capita rate of payment for each class of individuals who are so enrolled with such an organization and who are enrolled under part B only.

For purposes of this section, the term "risk-sharing contract" means a contract entered into under subsection (g) and the term "reasonable cost reimbursement contract" means a contract entered into under subsection (h).

(B) The Secretary shall define appropriate classes of members, based on age, disability status, and such other factors as the Secretary determines to be appropriate, so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such classes, if such changes will improve the determination of actuarial equivalence.

(C) The annual per capita rate of payment for each such class shall be equal to 95 percent of the adjusted average per capita cost (as defined in paragraph (4)) for that class.

(D) In the case of an eligible organization with a risk-sharing contract, the Secretary shall make monthly payments in advance and in accordance

with the rate determined under subparagraph (C) and except as provided in subsection (g)(2), to the organization for each individual enrolled with the organization under this section.

(E)(i) The amount of payment under this paragraph may be retroactively adjusted to take into account any difference between the actual number of individuals enrolled in the plan under this section and the number of such individuals estimated to be so enrolled in determining the amount of the advance payment.

(ii)(I) Subject to subclause (II), the Secretary may make retroactive adjustments under clause (i) to take into account individuals enrolled during the period beginning on the date on which the individual enrolls with an eligible organization (which has a risk-sharing contract under this section) under a health benefit plan operated, sponsored, or contributed to by the individual's employer or former employer (or the employer or former employer of the individual's spouse) and ending on the date on which the individual is enrolled in the plan under this section, except that for purposes of making such retroactive adjustments under this clause, such period may not exceed 90 days.

(II) No adjustment may be made under subclause (I) with respect to any individual who does not certify that the organization provided the individual with the explanation described in subsection (c)(3)(E) at the time the individual enrolled with the organization.

(F)(i) At least 45 days before making the announcement under subparagraph (A) for a year

(beginning with the announcement for 1991), the Secretary shall provide for notice to eligible organizations of proposed changes to be made in the methodology or benefit coverage assumptions from the methodology and assumptions used in the previous announcement and shall provide such organizations an opportunity to comment on such proposed changes.

(ii) In each announcement made under subparagraph (A) for a year (beginning with the announcement for 1991), the Secretary shall include an explanation of the assumptions (including any benefit coverage assumptions) and changes in methodology used in the announcement in sufficient detail so that eligible organizations can compute per capita rates of payment for classes of individuals located in each county (or equivalent area) which is in whole or in part within the service area of such an organization.

(2) With respect to any eligible organization which has entered into a reasonable cost reimbursement contract, payments shall be made to such plan in accordance with subsection (h)(2) rather than paragraph (1).

(3) Subject to subsections (c)(2)(B)(ii) and (c)(7), payments under a contract to an eligible organization under paragraph (1) or (2) shall be instead of the amounts which (in the absence of the contract) would be otherwise payable, pursuant to sections 1814(b) and 1833(a), for services furnished by or through the organization to individuals enrolled with the organization under this section.

(4) For purposes of this section, the term "adjusted average per capita cost" means the average per capita amount that the Secretary estimates in advance (on the

basis of actual experience, or retrospective actuarial equivalent based upon an adequate sample and other information and data, in a geographic area served by an eligible organization or in a similar area, with appropriate adjustments to assure actuarial equivalence) would be payable in any contract year for services covered under parts A and B, or part B only, and types of expenses otherwise reimbursable under parts A and B, or part B only (including administrative costs incurred by organizations described in sections 1816 and 1842), if the services were to be furnished by other than an eligible organization or, in the case of services covered only under section 1861(s)(2)(H), if the services were to be furnished by a physician or as an incident to a physician's service.

(5) The payment to an eligible organization under this section for individuals enrolled under this section with the organization and entitled to benefits under part A and enrolled under part B of this subchapter shall be made from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The portion of that payment to the organization for a month to be paid by each trust fund shall be determined as follows:

(A) In regard to expenditures by eligible organizations having risk-sharing contracts, the allocation shall be determined each year by the Secretary based on the relative weight that benefits from each fund contribute to the adjusted average per capita cost.

(B) In regard to expenditures by eligible organizations operating under a reasonable cost reimbursement contract, the initial allocation shall be based on

the plan's most recent budget, such allocation to be adjusted, as needed, after cost settlement to reflect the distribution of actual expenditures.

The remainder of that payment shall be paid by the former trust fund.

(6) Subject to subsections (c)(2)(B)(ii) and (c)(7), if an individual is enrolled under this section with an eligible organization having a risk-sharing contract, only the eligible organization shall be entitled to receive payments from the Secretary under this title for services furnished to the individual.

(b) For purposes of this section, the term "eligible organization" means a public or private entity (which may be a health maintenance organization or a competitive medical plan), organized under the laws of any State, which –

(1) is a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act), or

(2) meets the following requirements:

(A) The entity provides to enrolled members at least the following health care services:

(i) Physicians' services performed by physicians (as defined in section 1861(r)(1)).

(ii) Inpatient hospital services.

(iii) Laboratory, X-ray, emergency, and preventive services.

(iv) Out-of-area coverage.

(B) The entity is compensated (except for deductibles, coinsurance, and copayments) for the provision of health care services to enrolled members by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health care service actually provided to a member.

(C) The entity provides physicians' services primarily (i) directly through physicians who are either employees or partners of such organization, or (ii) through contracts with individual physicians or one or more groups of physicians (organized on a group practice or individual practice basis).

(D) The entity assumes full financial risk on a prospective basis for the provision of the health care services listed in subparagraph (A), except that such entity may –

(i) obtain insurance or make other arrangements for the cost of providing to any enrolled member health care services listed in subparagraph (A) the aggregate value of which exceeds $5,000 in any year,

(ii) obtain insurance or make other arrangements for the cost of health care service listed in subparagraph (A) provided to its enrolled members other than through the entity because medical necessity required their provision before they could be secured through the entity,

(iii) obtain insurance or make other arrangements for not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for such fiscal year, and

(iv) make arrangements with physicians or other health professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions.

(E) The entity has made adequate provision against the risk of insolvency, which provision is satisfactory to the Secretary.

Paragraph (2)(A)(ii) shall not apply to an entity which had contracted with a single State agency administering a State plan approved under title XIX of this chapter for the provision of services (other than inpatient hospital services) to individuals eligible for such services under such State plan on a prepaid risk basis prior to 1970.

(c)(1) The Secretary may not enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection and subsection (e) with respect to members enrolled under this section.

(2)(A) The organization must provide to members enrolled under this section, through providers and other persons that meet the applicable requirements of this title and part A of title XI –

(i) only those services covered under parts A and B of this title, for those members entitled to

benefits under part A and enrolled under part B, or

(ii) only those services covered under part B, for those members enrolled only under such part,

which are available to individuals residing in the geographic area served by the organization, except that (I) the organization may provide such members with such additional health care services as the members may elect, at their option, to have covered, and (II) in the case of an organization with a risk-sharing contract, the organization may provide such members with such additional health care services as the Secretary may approve. The Secretary shall approve any such additional health care services which the organization proposes to offer to such members, unless the Secretary determines that including such additional services will substantially discourage enrollment by covered individuals with the organization.

(B) If there is a national coverage determination made in the period beginning on the date of an announcement under subsection (a)(1)(A) and ending on the date of the next announcement under such subsection that the Secretary projects will result in a significant change in the costs to the organization of providing the benefits that are the subject of such national coverage determination and that was not incorporated in the determination of the per capita rate of payment included in the announcement made at the beginning of such period –

(i) such determination shall not apply to risk-sharing contracts under this section until the first contract year that begins after the end of such period; and

(ii) if such coverage determination provides for coverage of additional benefits or under additional circumstances, subsection (a)(3) shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period,

unless otherwise required by law.

(3)(A)(i) Each eligible organization must have an open enrollment period, for the enrollment of individuals under this section, of at least 30 days duration every year and including the period or periods specified under clause (ii), and must provide that at any time during which enrollments are accepted, the organization will accept up to the limits of its capacity (as determined by the Secretary) and without restrictions, except as may be authorized in regulations, individuals who are eligible to enroll under subsection (d) in the order in which they apply for enrollment, unless to do so would result in failure to meet the requirements of subsection (f) or would result in the enrollment of enrollees substantially nonrepresentative, as determined in accordance with regulations of the Secretary, of the population in the geographic area served by the organization.

(ii)(I) If a risk-sharing contract under this section is not renewed or is otherwise terminated, eligible organizations with risk-sharing contracts under this section and serving a part of the same service area as under the terminated contract are required to have an open enrollment period for individuals who were enrolled under the terminated contract as of the date of notice of such termination. If a risk-sharing contract under this section is

renewed in a manner that discontinues coverage for individuals residing in part of the service area, eligible organizations with risk-sharing contracts under this section and enrolling individuals residing in that part of the service area are required to have an open enrollment period for individuals residing in the part of the service area who were enrolled under the contract as of the date of notice of such discontinued coverage.

(II) The open enrollment periods required under subclause (I) shall be for 30 days and shall begin 30 days after the date that the Secretary provides notice of such requirement.

(III) Enrollment under this clause shall be effective 30 days after the end of the open enrollment period, or, if the Secretary determines that such date is not feasible, such other date as the Secretary specifies.

(B) An individual may enroll under this section with an eligible organization in such manner as may be prescribed in regulations and may terminate his enrollment with the eligible organization as of the beginning of the first calendar month following the date on which the request is made for such termination (or, in the case of financial insolvency of the organization, as may be prescribed by regulations) or, in the case of such an organization with a reasonable cost reimbursement contract, as may be prescribed by regulations.

(C) The Secretary may prescribe the procedures and conditions under which an eligible organization that has entered into a contract with the Secretary under this subsection may inform individuals eligible to enroll

under this section with the organization about the organization, or may enroll such individuals with the organization. No brochures, application forms, or other promotional or informational material may be distributed by an organization to (or for the use of) individuals eligible to enroll with the organization under this section unless (i) at least 45 days before its distribution, the organization has submitted the material to the Secretary for review and (ii) the Secretary has not disapproved the distribution of the material. The Secretary shall review all such material submitted and shall disapprove such material if the Secretary determines, in the Secretary's discretion, that the material is materially inaccurate or misleading or otherwise makes a material misrepresentation.

(D) The organization must provide assurances to the Secretary that it will not expel or refuse to re-enroll any such individual because of the individual's health status or requirements for health care services, and that it will notify each such individual of such fact at the time of the individual's enrollment.

(E) Each eligible organization shall provide each enrollee, at the time of enrollment and not less frequently than annually thereafter, an explanation of the enrollee's rights under this section, including an explanation of –

(i) the enrollee's rights to benefits from the organization,

(ii) the restrictions on payments under this title for services furnished other than by or through the organization,

(iii) out-of-area coverage provided by the organization,

(iv) the organization's coverage of emergency services and urgently needed care, and

(v) appeal rights of enrollees.

(F) Each eligible organization that provides items and services pursuant to a contract under this section shall provide assurances to the Secretary that in the event the organization ceases to provide such items and services, the organization shall provide or arrange for supplemental coverage of benefits under this title related to a pre-existing condition with respect to any exclusion period, to all individuals enrolled with the entity who receive benefits under this title, for the lesser of six months or the duration of such period.

(G)(i) Each eligible organization having a risk-sharing contract under this section shall notify individuals eligible to enroll with the organization under this section and individuals enrolled with the organization under this section that –

(I) the organization is authorized by law to terminate or refuse to renew the contract, and

(II) termination or nonrenewal of the contract may result in termination of the enrollments of individuals enrolled with the organization under this section.

(ii) The notice required by clause (i) shall be included in –

(I) any marketing materials described in subparagraph (C) that are distributed by an eligible

organization to individuals eligible to enroll under this section with the organization, and

(II) any explanation provided to enrollees by the organization pursuant to subparagraph (E).

(4) The organization must –

(A) make the services described in paragraph (2) (and such other health care services as such individuals have contracted for) (i) available and accessible to each such individual, within the area served by the organization, with reasonable promptness and in a manner which assures continuity, and (ii) when medically necessary, available and accessible twenty-four hours a day and seven days a week, and

(B) provide for reimbursement with respect to services which are described in subparagraph (A) and which are provided to such an individual other than through the organization, if (i) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition and (ii) it was not reasonable given the circumstances to obtain the services through the organization.

(5)(A) The organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and members enrolled with the organization under this section.

(B) A member enrolled with an eligible organization under this section who is dissatisfied by reason of his failure to receive any health service to which he believes he is entitled and at no greater charge than he believes he is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the

same extent as is provided in section 205(b), and in any such hearing the Secretary shall make the eligible organization a party. If the amount in controversy is $1,000 or more, the individual or eligible organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section 205(g), and both the individual and the eligible organization shall be entitled to be parties to that judicial review. In applying sections 205(b) and 205(g) as provided in this subparagraph, and in applying section 205(l) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(6) The organization must have arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for health care services it provides to such individuals, which program (A) stresses health outcomes and (B) provides review by physicians and other health care professionals of the process followed in the provision of such health care services.

(7) A risk-sharing contract under this section shall provide that in the case of an individual who is receiving inpatient hospital services from a subsection (d) hospital (as defined in section 1886(d)(1)(B)) as of the effective date of the individual's –

(A) enrollment with an eligible organization under this section –

(i) payment for such services until the date of the individual's discharge shall be made

under this title as if the individual were not enrolled with the organization,

(ii) the organization shall not be financially responsible for payment for such services until the date after the date of the individual's discharge, and

(iii) the organization shall nonetheless be paid the full amount otherwise payable to the organization under this section; or

(B) termination of enrollment with an eligible organization under this section –

(i) the organization shall be financially responsible for payment for such services after such date and until the date of the individual's discharge,

(ii) payment for such services during the stay shall not be made under section 1886(d), and

(iii) the organization shall not receive any payment with respect to the individual under this section during the period the individual is not enrolled.

In the case of an individual's termination of enrollment, the organization shall provide the individual with a copy of the written request for termination of enrollment and a written explanation of the period (ending on the effective date of the termination) during which the individual continues to be enrolled with the organization and may not receive benefits under this title other than through the organization.

(8) A contract under this section shall provide that the eligible organization shall meet the requirement of

section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

(d) Subject to the provisions of subsection (c)(3), every individual entitled to benefits under part A and enrolled under part B or enrolled under part B only (other than an individual medically determined to have end-stage renal disease) shall be eligible to enroll under this section with any eligible organization with which the Secretary has entered into a contract under this section and which serves the geographic area in which the individual resides.

(e)(1) In no case may –

(A) the portion of an eligible organization's premium rate and the actuarial value of its deductibles, coinsurance, and copayments charged (with respect to services covered under parts A and B) to individuals who are enrolled under this section with the organization and who are entitled to benefits under part A and enrolled under part B, or

(B) the portion of its premium rate and the actuarial value of its deductibles, coinsurance, and copayments charged (with respect to services covered under part B) to individuals who are enrolled under this section with the organization and enrolled under part B only

exceed the actuarial value of the coinsurance and deductibles that would be applicable on the average to individuals enrolled under this section with the organization (or, if the Secretary finds that adequate data are not available to determine that actuarial value, the actuarial value of the coinsurance and deductibles applicable on the average to individuals in the area, in the State, or in the

United States, eligible to enroll under this section with the organization, or other appropriate data) and entitled to benefits under part A and enrolled under part B, or enrolled under part B only, respectively, if they were not members of an eligible organization.

(2) If the eligible organization provides to its members enrolled under this section services in addition to services covered under parts A and B of this title, election of coverage for such additional services (unless such services have been approved by the Secretary under subsection (c)(2)) shall be optional for such members and such organization shall furnish such members with information on the portion of its premium rate or other charges applicable to such additional services. In no case may the sum of –

(A) the portion of such organization's premium rate charged, with respect to such additional services, to members enrolled under this section, and

(B) the actuarial value of its deductibles, coinsurance, and copayments charged, with respect to such services to such members

exceed the adjusted community rate for such services.

(3) For purposes of this section, the term "adjusted community rate" for a service or services means, at the election of an eligible organization, either –

(A) the rate of payment for that service or services which the Secretary annually determines would apply to a member enrolled under this section with an eligible organization if the rate of payment were determined under a "community rating system" (as defined in section 1302(8) of the Public Health Service Act, other than subparagraph (C)), or

(B) such portion of the weighted aggregate premium, which the Secretary annually estimates would apply to a member enrolled under this section with the eligible organization, as the Secretary annually estimates is attributable to that service or services,

but adjusted for differences between the utilization characteristics of the members enrolled with the eligible organization under this section and the utilization characteristics of the other members of the organization (or, if the Secretary finds that adequate data are not available to adjust for those differences, the differences between the utilization characteristics of members in other eligible organizations, or individuals in the area, in the State, or in the United States, eligible to enroll under this section with an eligible organization and the utilization characteristics of the rest of the population in the area, in the State, or in the United States, respectively).

(4) Notwithstanding any other provision of law, the eligible organization may (in the case of the provision of services to a member enrolled under this section for an illness or injury for which the member is entitled to benefits under a workmen's compensation law or plan of the United States or a State, under an automobile or liability insurance policy or plan, including a self-insured plan, or under no fault insurance) charge or authorize the provider of such services to charge, in accordance with the charges allowed under such law or policy –

(A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services, or

(B) such member to the extent that the member has been paid under such law, plan, or policy for such services.

(f)(1) For contract periods beginning before January 1, 1999, each eligible organization with which the Secretary enters into a contract under this section shall have, for the duration of such contract, an enrolled membership at least one-half of which consists of individuals who are not entitled to benefits under this title.

(2) Subject to paragraph (4), The Secretary may modify or waive the requirement imposed by paragraph (1) –

(A) to the extent that more than 50 percent of the population of the area served by the organization consists of individuals who are entitled to benefits under this title or under a State plan approved under title XIX, or

(B) in the case of an eligible organization that is owned and operated by a governmental entity, only with respect to a period of three years beginning on the date the organization first enters into a contract under this section, and only if the organization has taken and is making reasonable efforts to enroll individuals who are not entitled to benefits under this title or under a State plan approved under title XIX.

(3) If the Secretary determines that an eligible organization has failed to comply with the requirements of this subsection, the Secretary may provide for the suspension of enrollment of individuals under this section or of payment to the organization under this section for individuals newly enrolled with the organization, after the

date the Secretary notifies the organization of such non-compliance.

(4) Effective for contract periods beginning after December 31, 1996, the Secretary may waive or modify the requirement imposed by paragraph (1) to the extent the Secretary finds that it is in the public interest.

(g)(1) The Secretary may enter a risk-sharing contract with any eligible organization, as defined in subsection (b), which has at least 5,000 members, except that the Secretary may enter into such a contract with an eligible organization that has fewer members if the organization primarily serves members residing outside of urbanized areas.

(2) Each risk-sharing contract shall provide that –

(A) if the adjusted community rate, as defined in subsection (e)(3), for services under parts A and B (as reduced for the actuarial value of the coinsurance and deductibles under those parts) for members enrolled under this section with the organization and entitled to benefits under part A and enrolled in part B, or

(B) if the adjusted community rate for services under part B (as reduced for the actuarial value of the coinsurance and deductibles under that part) for members enrolled under this section with the organization and entitled to benefits under part B only is less than the average of the per capita rates to benefits under part B only

is less than the average of the per capita rates of payment to be made under subsection (a)(1) at the beginning of an annual contract period for members enrolled under this section with the organization and entitled to benefits

under part A and enrolled in part B, or enrolled in part B only, respectively, the eligible organization shall provide to members enrolled under a risk-sharing contract under this section with the organization and entitled to benefits under part A and enrolled in part B, or enrolled in part B only, respectively, the additional benefits described in paragraph (3) which are selected by the eligible organization and which the Secretary finds are at least equal in value to the difference between that average per capita payment and the adjusted community rate (as so reduced); except that this paragraph shall not apply with respect to any organization which elects to receive a lesser payment to the extent that there is no longer a difference between the average per capita payment and adjusted community rate (as so reduced) and except that an organization (with the approval of the Secretary) may provide that a part of the value of such additional benefits be withheld and reserved by the Secretary as provided in paragraph (5). If the Secretary finds that there is insufficient enrollment experience to determine an average of the per capita rates of payment to be made under subsection (a)(1) at the beginning of a contract period, the Secretary may determine such an average based on the enrollment experience of other contracts entered into under this section.

(3) The additional benefits referred to in paragraph (2) are –

(A) the reduction of the premium rate or other charges made with respect to services furnished by the organization to members enrolled under this section, or

(B) the provision of additional health benefits,

or both.

(4) [Repealed.]

(5) An organization having a risk-sharing contract under this section may (with the approval of the Secretary) provide that a part of the value of additional benefits otherwise required to be provided by reason of paragraph (2) be withheld and reserved in the Federal Hospital Insurance Trust Fund and in the Federal Supplementary Medical Insurance Trust Fund (in such proportions as the Secretary determines to be appropriate) by the Secretary for subsequent annual contract periods, to the extent required to stabilize and prevent undue fluctuations in the additional benefits offered in those subsequent periods by the organization in accordance with paragraph (3). Any of such value of additional benefits which is not provided to members of the organization in accordance with paragraph (3) prior to the end of such period, shall revert for the use of such trust funds.

(6)(A) A risk-sharing contract under this section shall require the eligible organization to provide prompt payment (consistent with the provisions of sections 1816(c)(2) and 1842(c)(2)) of claims submitted for services and supplies furnished to individuals pursuant to such contract, if the services or supplies are not furnished under a contract between the organization and the provider or supplier.

(B) In the case of an eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with subparagraph (A), the Secretary may provide for direct payment of the amounts owed to providers and suppliers for such covered services furnished to individuals enrolled under this section under the contract. If the Secretary provides for such direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this section to reflect the amount of the Secretary's payments (and costs incurred by the Secretary in making such payments).

(h)(1) If –

(A) the Secretary is not satisfied that an eligible organization has the capacity to bear the risk of potential losses under a risk-sharing contract under this section, or

(B) the eligible organization so elects or has an insufficient number of members to be eligible to enter into a risk-sharing contract under subsection (g)(1),

the Secretary may, if he is otherwise satisfied that the eligible organization is able to perform its contractual obligations effectively and efficiently, enter into a contract with such organization pursuant to which such organization is reimbursed on the basis of its reasonable cost (as defined in section 1861(v)) in the manner prescribed in paragraph (3).

(2) A reasonable cost reimbursement contract under this subsection may, at the option of such organization, provide that the Secretary –

(A) will reimburse hospitals and skilled nursing facilities either for the reasonable cost (as determined under section 1861(v)) or for payment amounts determined in accordance with section 1886, as applicable, of services furnished to individuals enrolled with such organization pursuant to subsection (d), and

(B) will deduct the amount of such reimbursement from payment which would otherwise be made to such organization.

If such an eligible organization pays a hospital or skilled nursing facility directly, the amount paid shall not exceed the reasonable cost of the services (as determined under section 1861(v)) or the amount determined under section 1886, as applicable, unless such organization demonstrates to the satisfaction of the Secretary that such excess payments are justified on the basis of advantages gained by the organization.

(3) Payments made to an organization with a reasonable cost reimbursement contract shall be subject to appropriate retroactive corrective adjustment at the end of each contract year so as to assure that such organization is paid for the reasonable cost actually incurred (excluding any part of incurred cost found to be unnecessary in the efficient delivery of health services) or the amounts otherwise determined under section 1886 for the types of expenses otherwise reimbursable under this title for providing services covered under this title to individuals described in subsection (a)(1).

(4) Any reasonable cost reimbursement contract with an eligible organization under this subsection shall provide that the Secretary shall require, at such time following the expiration of each accounting period of the eligible organization (and in such form and in such detail) as he may prescribe –

(A) that the organization report to him in an independently certified financial statement its per capita incurred cost based on the types of components of expenses otherwise reimbursable under this title for providing services described in subsection (a)(1), including therein, in accordance with accounting procedures prescribed by the Secretary, its methods of allocating costs between individuals enrolled under this section and other individuals enrolled with such organization;

(B) that failure to report such information as may be required may be deemed to constitute evidence of likely overpayment on the basis of which appropriate collection action may be taken;

(C) that in any case in which an eligible organization is related to another organization by common ownership or control, a consolidated financial statement shall be filed and that the allowable costs for such organization may not include costs for the types of expense otherwise reimbursable under this title, in excess of those which would be determined to be reasonable in accordance with regulations (providing for limiting reimbursement to costs rather than charges to the eligible organization by related organizations and owners) issued by the Secretary; and

(D) that in any case in which compensation is paid by an eligible organization substantially in excess of what is normally paid for similar services by similar practitioners (regardless of method of

compensation), such compensation may as appropriate be considered to constitute a distribution of profits.

(5)(A) After the date of the enactment of this paragraph, the Secretary may not enter into a reasonable cost reimbursement contract under this subsection (if the contract is not in effect as of such date), except for a contract with an eligible organization which, immediately previous to entering into such contract, had an agreement in effect under section 1833(a)(1)(A).

(B) The Secretary may not extend or renew a reasonable cost reimbursement contract under this subsection for any period beyond December 31, 2002.

(i)(1) Each contract under this section shall be for a term of at least one year, as determined by the Secretary, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term; except that in accordance with procedures established under paragraph (9), the Secretary may at any time terminate any such contract or may impose the intermediate sanctions described in paragraph (6)(B) or (6)(C) (whichever is applicable) on the eligible organization if the Secretary determines that the organization –

(A) has failed substantially to carry out the contract;

(B) is carrying out the contract in a manner substantially inconsistent with the efficient and effective administration of this section; or

(C) no longer substantially meets the applicable conditions of subsections (b), (c), (e), and (f).

(2) The effective date of any contract executed pursuant to this section shall be specified in the contract.

(3) Each contract under this section –

(A) shall provide that the Secretary, or any person or organization designated by him –

(i) shall have the right to inspect or otherwise evaluate (I) the quality, appropriateness, and timeliness of services performed under the contract and (II) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

(ii) shall have the right to audit and inspect any books and records of the eligible organization that pertain (I) to the ability of the organization to bear the risk of potential financial losses, or (II) to services performed or determinations of amounts payable under the contract;

(B) shall require the organization with a risk-sharing contract to provide (and pay for) written notice in advance of the contract's termination, as well as a description of alternatives for obtaining benefits under this title, to each individual enrolled under this section with the organization; and

(C)(i) shall require the organization to comply with subsections (a) and (c) of section 1318 of the Public Health Service Act (relating to disclosure of certain financial information) and with the requirement of section 1301(c)(8) of such Act (relating to liability arrangements to protect members);

(ii) shall require the organization to provide and supply information (described in section 1866(b)(2)(C)(ii))) in the manner such information is required to be provided or supplied under that section;

(iii) shall require the organization to notify the Secretary of loans and other special financial arrangements which are made between the organization and subcontractors, affiliates, and related parties; and

(D) shall contain such other terms and conditions not inconsistent with this section (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

(4) The Secretary may not enter into a risk-sharing contract with an eligible organization if a previous risk-sharing contract with that organization under this section was terminated at the request of the organization within the preceding five-year period, except in circumstances which warrant special consideration, as determined by the Secretary.

(5) The authority vested in the Secretary by this section may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this title.

(6)(A) If the Secretary determines that an eligible organization with a contract under this section –

(i) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(ii) imposes premiums on individuals enrolled under this section in excess of the premiums permitted;

(iii) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this section;

(iv) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this section) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(v) misrepresents or falsifies information that is furnished –

(I) to the Secretary under this section, or

(II) to an individual or to any other entity under this section;

(vi) fails to comply with the requirements of subsection (g)(6)(A) or paragraph (8); or

(vii) in the case of a risk-sharing contract, employs or contracts with any individual or entity that is excluded from participation under this title under section 1128 or 1128A for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services;

the Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in subparagraph (B).

(B) The remedies described in this subparagraph are –

(i) civil money penalties of not more than $25,000 for each determination under subparagraph (A) or, with respect to a determination under clause (iv) or (v)(I), of not more than $100,000 for each such determination, plus, with respect to a determination under subparagraph (A)(ii), double the excess amount charged in violation of such subparagraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under subparagraph (A)(iv), $15,000 for each individual not enrolled as a result of the practice involved,

(ii) suspension of enrollment of individuals under this section after the date the Secretary notifies the organization of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur, or

(iii) suspension of payment to the organization under this section for individuals enrolled after the date the Secretary notifies the organization of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

(C) In the case of an eligible organization for which the Secretary makes a determination under paragraph (1), the basis of which is not described in subparagraph (A), the Secretary may apply the following intermediate sanctions:

(i) Civil money penalties of not more than $25,000 for each determination under paragraph

(1) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

(ii) Civil money penalties of not more than $10,000 for each week beginning after the initiation of procedures by the Secretary under paragraph (9) during which the deficiency that is the basis of a determination under paragraph (1) exists.

(iii) Suspension of enrollment of individuals under this section after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.

(D) The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under subparagraph (B)(i) or (C)(i) in the same manner as such provisions apply to a civil money penalty or proceeding under section 1128A(a).

(7)(A) Each risk-sharing contract with an eligible organization under this section shall provide that the organization will maintain a written agreement with a utilization and quality control peer review organization (which has a contract with the Secretary under part B of title XI of this chapter for the area in which the eligible organization is located) or with an entity selected by the Secretary under section 1154(a)(4)(C) under which the review organization will perform functions under section 1154(a)(4)(B) and section 1154(a)(14) (other than those performed under contracts described in section

1866(a)(I)(F)) with respect to services, furnished by the eligible organization, for which payment may be made under this title.

(B) For purposes of payment under this title, the cost of such agreement to the eligible organization shall be considered a cost incurred by a provider of services in providing covered services under this title and shall be paid directly by the Secretary to the review organization on behalf of such eligible organization in accordance with a schedule established by the Secretary.

(C) Such payments –

(i) shall be transferred in appropriate proportions from the Federal Hospital Insurance Trust Fund and from the Supplementary Medical Insurance Trust Fund, without regard to amounts appropriated in advance in appropriation Acts, in the same manner as transfers are made for payment for services provided directly to beneficiaries, and

(ii) shall not be less in the aggregate for such organizations for a fiscal year than the amounts the Secretary determines to be sufficient to cover the costs of such organizations conducting activities described in subparagraph (A) with respect to such eligible organizations under part B of title XI.

(8)(A) Each contract with an eligible organization under this section shall provide that the organization may not operate any physician incentive plan (as defined in subparagraph (B)) unless the following requirements are met:

(i) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the organization.

(ii) If the plan places a physician or physician group at substantial financial risk (as determined by the Secretary) for services not provided by the physician or physician group, the organization –

(I) provides stop-loss protection for the physician or group that is adequate and appropriate, based on standards developed by the Secretary that take into account the number of physicians placed at such substantial financial risk in the group or under the plan and the number of individuals enrolled with the organization who receive services from the physician or the physician group, and

(II) conducts periodic surveys of both individuals enrolled and individuals previously enrolled with the organization to determine the degree of access of such individuals to services provided by the organization and satisfaction with the quality of such services.

(iii) The organization provides the Secretary with descriptive information regarding the plan, sufficient to permit the Secretary to determine whether the plan is in compliance with the requirements of this subparagraph.

(B) In this paragraph, the term "physician incentive plan" means any compensation arrangement between an eligible organization and a physician or physician group that may directly or

indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the organization.

(9) The Secretary may terminate a contract with an eligible organization under this section or may impose the intermediate sanctions described in paragraph (6) on the organization in accordance with formal investigation and compliance procedures established by the Secretary under which –

(A) the Secretary first provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under paragraph (1) and the organization fails to develop or implement such a plan;

(B) in deciding whether to impose sanctions, the Secretary considers aggravating factors such as whether an organization has a history of deficiencies or has not taken action to correct deficiencies the Secretary has brought to the organization's attention;

(C) there are no unreasonable or unnecessary delays between the finding of a deficiency and the imposition of sanctions; and

(D) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before imposing any sanction or terminating the contract.

(j)(1)(A) In the case of physicians' services or renal dialysis services described in paragraph (2) which are furnished by a participating physician or provider of services or renal dialysis facility to an individual enrolled with an eligible organization under this section and

enrolled under part B, the applicable participation agreement is deemed to provide that the physician or provider of services or renal dialysis facility will accept as payment in full from the eligible organization the amount that would be payable to the physician or provider of services or renal dialysis facility under part B and from the individual under such part, if the individual were not enrolled with an eligible organization under this section.

(B) In the case of physicians' services described in paragraph (2) which are furnished by a nonparticipating physician, the limitations on actual charges for such services otherwise applicable under part B (to services furnished by individuals not enrolled with an eligible organization under this section) shall apply in the same manner as such limitations apply to services furnished to individuals not enrolled with such an organization.

(2) The physicians' services or renal dialysis services described in this paragraph are physicians' services or renal dialysis services which are furnished to an enrollee of an eligible organization under this section by a physician, provider of services, or renal dialysis facility who is not under a contract with the organization.

(k)(1) Except as provided in paragraph (2) –

(A) on or after the date standards for Medicare +Choice organizations and plans are first established under section 1856(b)(1), the Secretary shall not enter into any risksharing contract under this section with an eligible organization; and

(B) for any contract year beginning on or after January 1, 1999, the Secretary shall not renew any such contract.

(2) An individual who is enrolled in part B only and is enrolled in an eligible organization with a risk-

sharing contract under this section on December 31, 1998, may continue enrollment in such organization in accordance with regulations described in section 1856(b)(1).

(3) Notwithstanding subsection (a), the Secretary shall provide that payment amounts under risk-sharing contracts under this section for months in a year (beginning with January 1998) shall be computed –

(A) with respect to individuals entitled to benefits under both parts A and B, by substituting payment rates under section 1853(a) for the payment rates otherwise established under section 1876(a), and

(B) with respect to individuals only entitled to benefits under part B, by substituting an appropriate proportion of such rates (reflecting the relative proportion of payments under this title attributable to such part) for the payment rates otherwise established under subsection (a).

(4) The following requirements shall apply to eligible organizations with risk-sharing contracts under this section in the same manner as they apply to Medicare +Choice organizations under part C;

(A) Data collection requirements under section 1853(a)(3)(B).

(B) Restrictions on imposition of premium taxes under section 1854(g) in relating to payments to such organizations under this section.

(C) The requirement to accept enrollment of new enrollees during November 1998 under section 1851(e)(6).

(D) Payments under section 1857(e)(2).